

**Francer, Jeffrey**

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**From:** Zavagno, Denise  
**Sent:** Friday, October 08, 2004 10:57 AM  
**To:** Azar, Alex (OS); Stannard, Paula (OS); Troy, Daniel; Hargan, Eric (OS)  
**Cc:** Raza, Mark; Francer, Jeffrey  
**Subject:** FW: Suspension of Manufacturer's Licence  
**Importance:** High  
**Sensitivity:** Confidential

Alex: I understand you had wanted to review anything forwarded to FDA by Ms. Sinclair-Jenkins in response to the questions I forwarded on Wednesday, October 6. Her response is attached. Please do not hesitate to call me with questions or comments.

Denise Zavagno  
Food & Drug Division, OGC  
301-827-1134

-----Original Message-----

**From:** Sinclair-Jenkins, Bernadette [mailto:Bernadette.Sinclair-Jenkins@mhra.gsi.gov.uk]  
**Sent:** Friday, October 08, 2004 9:58 AM  
**To:** dzavagno@oc.fda.gov  
**Cc:** markraza@oc.fda.gov  
**Subject:** RE: Suspension of Manufacturer's Licence  
**Importance:** High  
**Sensitivity:** Confidential

Dear Ms Zavagno

Please find attached a reply to your e-mail of 6 October and an extract of the relevant UK legislation.

Yours sincerely

Bernadette Sinclair-Jenkins  
**Unit Manager, Policy and Borderline**  
**MHRA**

<<Suspension of Manufacturer's Licence.doc>> <<Scanned document.jpg>>

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Friday 8<sup>th</sup> October 2004

Ms Zavagno  
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Dear Ms Zavagno

### **Suspension of Manufacturer's Licence**

Thank you for your e-mail of 6 October about the suspension of the Chiron Manufacturer's Licence for influenza vaccination products (ML 18532/01).

I will answer your questions in the order in which you raised them:

1. Section 28 of the Medicines Act 1968 (the "Act") provides powers to suspend, revoke or vary a licence under the Act. Schedule 2 to the Act sets out the procedure to be followed by the licensing authority in exercising these powers. Chiron's Manufacturer's Licence was suspended with immediate effect in accordance with paragraph 11 of Schedule 2. There is no appeal mechanism for an immediate suspension. Chiron's licence has been suspended for 3 months.

2. The licence suspension prevents any manufacturing activity from the date specified ie. ~~October 6<sup>th</sup>~~ October 5<sup>th</sup>.

The date of March 2, 2004 was specified in the suspension letter because that was the date that the company first found high levels of bio burden in the intermediate product ~~monovalent blend pools~~.

3. I understand that no batches of product were released to market prior to the suspension of the licence. Each batch of product must be certified by a Qualified Person prior to release for sale. For your information I attach a copy of the relevant UK legislation (paragraph 16 of the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971, SI 1971/972). Certification of product is a manufacturing activity, ie. it is an activity carried out under a Manufacturer's Licence. Hence if certification had not taken place before the suspension of the licence, it cannot now take place.

I trust that I have satisfactorily answered your questions.

Yours sincerely

Bernadette Sinclair-Jenkins  
Unit Manager, Policy and Borderline  
MHRA